

REMARKS

Claims 1-26 are currently pending in the application. Claims 1 and 24 have been amended to recite, as suggested by the Examiner, that tensile strength measurement is with respect to a compact consisting only of the starch. Support is found at paragraph 18 of the specification. Claims 1 and 24 have also been amended to recite that the claimed tablet provides sustained release as compared with an immediate release pramipexole formulation. Support is found at Examples 10 and 11, including at paragraph 132. Claim 24 is also amended to depend only from claim 1 and to include limitations of claim 25. Claim 25 is amended to include the composition limitations of claim 23.

Rejection Under 35 USC § 112

Claims 1-26 stand rejected under 35 USC § 112, second paragraph, as indefinite on the basis that “at a solid fraction representative of the tablet” is unclear. The Examiner suggests reciting that the tensile strength of the starch is determined by use of a starch compact containing only the claimed starch. This has been done.

The Examiner indicates that further amendment is required to define the parameters used in preparing the sample for tensile strength measurement. It is respectfully submitted that the parameters are accounted for in the recitation of measurement taken at a solid fraction representative of the tablet, e.g., 0.8 as in claim 23. The specification discloses that e.g., in the triaxial tensile strength test (see [0046]), the solid fraction is calculated after compression, and thus reflects that parameter. It is noted that compression is the varying parameter in the tensile strength tables of the Michaud reference cited in a rejection under 35 U.S.C. 103. Thus, this appears accounted for in the recited tensile strength parameter. A conference may be helpful should this remain a basis for rejection.

Rejections Under 35 USC § 102

Claims 1-4, 8-9, 13-20, and 24-26 stand rejected under 35 U.S.C. 102(e) as anticipated by the Holman reference. Claims 1-4, 8-14, 19-20, 22, 24, and 26 stand rejected under 35 U.S.C. 102(e) as anticipated by the Patel reference. The Examiner states that the references disclose compositions which inherently have the properties of the claimed composition. In view of the amendments to the claims and remarks below, applicants respectfully traverse this

rejection.

Claim 1, from which the rejected claims depend, has been amended to recite that the tablet provides sustained release as compared with an immediate release pramipexole formulation.

The Holman reference describes administration of Mirapex to treat fibromyalgia. Mirapex is an immediate release formulation of pramipexole and is, it is submitted, clearly distinguished to one skilled in this art, particularly in view of the present specification, from the claimed composition. It is noted that the Mirapex formulation is indicated to be immediate release in the present specification at page 24, Table 12. In view of this teaching, and other skill in the art, those of ordinary skill would not, it is submitted, interpret the rejected claims as encompassing the Mirapex formulation of the Holman reference, and would instead interpret them as distinguished.

The Patel publication discloses many hundreds of pharmaceutically active agents, in a general description of many types of formulations, and using many types of excipients. The first stated object of the invention is to provide active ingredients in a rapid dissolvable state. It is respectfully submitted that the Patel reference cannot form a proper basis for a rejection of the cited claims on the basis of anticipation, as it does not clearly disclose the claimed invention to one of ordinary skill. Rather, to arrive at the invention would require combining elements from among many tens of thousands of possible combinations.

Withdrawal of the rejections under 35 U.S.C. 102(e) is respectfully requested on these bases.

Claims 1-22 and 24-26 stand rejected under 35 U.S.C. 103(a) as obvious over the Holman reference alone, or in view of the Michaud reference. Claims 1-26 are rejected under 35 U.S.C. 103(a) as unpatentable over Patel alone or in view of Michaud. Claims 1-26 are rejected under 35 U.S.C. 103(a) as obvious over Holman in view of Khan further in view of Petrus.

The Examiner indicates that there would have been motivation to combine starches exhibiting high tensile strengths from the Michaud reference to achieve hard tablets at low compression rates, and that this would have been an obvious production advantage. In view of the amendments to the claims and remarks below, Applicants respectfully traverse these rejections.

Claims 1 and 23 have been amended to distinguish more clearly the sustained release properties of the composition as compared with an immediate release pramipexole formulation. Claim 24 is further directed to a once daily method of administration of pramipexole in the

sustained release formulation.

None of the cited references, alone or in combination, teaches the employment of starches having the recited tensile strength property for the successful production of a composition of pramipexole which has sustained release properties as compared with an immediate release pramipexole formulation. While the Michaud reference teaches the use of starches exhibiting a range of tensile strengths, the teaching of this reference is to formulations which disintegrate at "very high speeds" (Abstract), i.e., immediate release formulations. It is unclear how this reference can properly be combined with the other references to arrive at a sustained release composition as claimed.

While the examiner cites an "obvious production advantage" for motivation, none of the references teach this with respect to the claimed composition, i.e., the sustained release composition of pramipexole as compared with an immediate release composition, or that this can be predictably accomplished by screening starches to obtain those exhibiting the recited tensile strength property.

Claims relating to a once a day method of treatment using a sustained release composition are submitted to be particularly removed from the references, and in particular from the three times a day pramipexole of the prior art. There is no suggestion of such a method.

For these reasons, withdrawal of the rejections under 35 U.S.C. 103(a) is respectfully requested.

Conclusion

In view of the remarks above, Applicants respectfully submit that the pending claims are now in condition for allowance and request issuance of a notice to that effect. If a telephone interview is deemed to be helpful to expedite the prosecution of the subject application, the Examiner is invited to contact applicants' undersigned attorneys at the telephone number provided.

The Commissioner is hereby authorized to charge any fees required or to credit any overpayment to Deposit Account No. 16-1445.

Respectfully submitted,

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